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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,170	08/07/2003	Gerald Horn	114711-012	2097

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EXAMINER

GIBSON, ROY DEAN

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 01/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/636,170

Applicant(s)

HORN ET AL.

Examiner

Roy D. Gibson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 16-23 and 25-36 is/are rejected.
- 7) ☒ Claim(s) 11-15 and 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/10/2003
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the apparatus of claims 28-36 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 6 is objected to because of the following informalities: "of on zonules" in line 2 apparently should be "of the zonules". Appropriate correction is required.

Claim 23 should end with a period.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Klopotek (5,230,334).

As to claim 1, Klopotek discloses a method of treating an eye, comprising the steps of:

identifying an area (target region) of an eye;
focusing a device capable of directing HIFU energy on the area;
generating HIFU energy from the device onto the area; wherein the energy transfer from the device to the area results in an increase in temperature of the area (col. 1, lines 12-22, col. 2, lines 1-10, 28-36 and 55-63, col. 3, lines 29-49 and col. 5, lines 4-8 and 32-43).

As to claims 2-3, Klopotek discloses that the energy transfer results in contracting the area thus increasing tension on a component of the eye in connection with a lens of the eye (col. 5, lines 32-43).

As to claims 20-22, Klopotek discloses that the HIFU energy heats the area to 60-70° C (col. 5, lines 4-8).

Claims 1-6, 8, 10, 16-17 and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Schachar (5,529,076).

As to claims 1, 8, 10 and 25-26, Schachar discloses a method of treating an eye, including a presbyopic eye comprising the steps of:

- identifying an area (longitudinal ciliary muscle or peripheral lens capsule) of an eye;
- focusing a device capable of directing focused ultrasound energy on the area;
- generating focused ultrasound energy from the device onto the area; wherein the energy transfer from the device to the area results in an increase in temperature of the area and results in alleviating presbyopia (the improvement of accommodation of the eye and col. 9, lines 3-31). Note that sharply focused energy beams are disclosed and that optional beams include laser and ultrasound, each of which would inherently increase the temperature in the targeted region.

As to claims 2-5, Schachar discloses that the energy transfer results in contracting the area thus increasing tension on a component of the eye (ciliary muscle)

in connection with a lens of the eye, wherein the contracting results in treating presbyopia (col. 9, lines 15-31 and col. 10, lines 3-23).

As to claim 6, Schachar discloses that the energy transfer results in contracting the lens capsule and increasing the tension in the zonules of the eye (col. 10, lines 12-23).

As to claims 16-17, Schachar discloses that the energy results in slowing lens diameter growth (col. 8, line 61-col. 9, line 11). Further to claim 17, it is inherent in the heating of the lens capsule that its modulus of elasticity would be altered.

As to claim 27, Schachar discloses a method of preventing presbyopia comprising the steps defined by claim 1 above and col. 8, lines 40-50).

Claims 28, 33, 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Driller et al. (4,484,569).

As to claims 28, 33 and 35, Driller et al. disclose an apparatus for ophthalmic therapy by generating HIFU energy comprising:

a transducer (20) comprising ceramic piezoelectric crystals operating at 4-10 MHz with an output from 5-10 watts (col. 2, lines 17-39, col. 3, lines 5-8 and 52-61).

As to claim 36, Driller et al. disclose a plurality of transducers (one for diagnostics, # 22 and one for treatment, # 20 (col. 3, lines 34-39).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 9, 18, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schachar ('076).

As to claims 7 and 9, Schachar fails to specifically disclose repeating of the application of the energy beam onto the zonules (col. 10, lines 12-17), however, the examiner maintains that it would have been obvious to one of ordinary skill in the art to continue a surgical procedure by examining the results of each application and repeating the application as required to accomplish the desired results.

As to claims 18 and 19, Schachar fails to specifically disclose the area being treated, however, the examiner maintains that it would have been obvious to a skillful artisan to select an area with no dimension larger than 1-2 mm as required to heat the specific muscles or zonules to accomplish the treatment of the presbyopic eye.

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schachar ('076) in view of Vaezy et al. (6,425,867).

As to claim 23, Schachar lacks the specific disclosure that the identifying step comprises applying ultrasound scanning imaging to identify the area. But, Vaezy et al. disclose HIFU treatment and scanning transducers combined for identifying the tissue to

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be treated prior to treatment (col. col. 9, lines 18-39 and 60-67 and col. 10, lines 12-36). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Schachar, as taught by Vaezy et al. to include ultrasonic scanning means to identify the treatment area. See also Coleman et al. (4,932,414) for ultrasonic scanning for imaging prior to treatment.

Claims 29-32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Driller ('569).

As to claims 29-32, Driller fails to specifically disclose the diameter, focal length and radius of curvature of the transducer, but the examiner maintains that it would have been obvious to a skillful artisan to select the appropriate dimensions of the transducer as required for the desired procedure. See also Martin et al. (6,217,530), col. 6, lines 18-43).

As to claim 34, Driller discloses the output of the transducer in the range of 5-10 watts (col. 3, lines 5-8). But, the examiner maintains that higher powers could be provided as required by the procedure, including the range of 100-300 watts.

Allowable Subject Matter

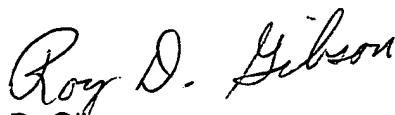
Claims 11-15 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on M-F, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Roy D. Gibson
Primary Examiner
Art Unit 3739

January 11, 2005